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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,882

07/24/2003

Marc Beauregard

15493-1US-1 MG/al

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08/02/2006

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/625,882

Applicant(s)

BEAUREGARD ET AL.

Examiner

Joseph T. Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 16-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application filed July 24, 2003, is a CIP of 10/272,929, filed 10/18/2002, which claims benefit of 60/329,759, filed 10/18/2001.

Claims 1-28 are pending.

### ***Election/Restrictions***

Applicants note that claims 26-28 depend on method claims, and more properly belong to groups XV-XX. Applicants indicate that they wish to have only claims 9-15 examined. Examiner noted the dependency of claims 26-28 to the method of claim 23 but included in the group drawn to a product for the sake of restriction. Examiner notes that claims 26-28 are improper dependent claims, i.e. a product dependent on a method, and as requested by Applicants will include these claims in a non-elected invention and withdraw the claims from examination.

Applicant's election of Group VI in the reply filed on May 15, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-28 are pending. Claims 1-7, 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 2006.

Art Unit: 1632

Claims 8-15, drawn to a protein encoded by SEQ ID NO: 1 or a fragment thereof wherein the sequence contains at least one substitution are currently under examination.

As noted previously, claim 8 links inventions VI-X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

In addition, it is noted that the method of Group I is related to the instantly claimed product of Group VI. In this case, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 8, 2006 and May 30, 2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

Claim 8 is objected to because of the following informalities:

First, claim 8 recites and is dependent in part on claim 1, which is a non-elected invention. Second, claim 8 recites and encompasses limitations, *i.e.* "or nucleic acid sequence" and SEQ ID NOs, directed to non-elected inventions.

Appropriate correction is required.

### ***Specification/Drawings***

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

Review of the drawings and the brief description of the drawings indicates that the sequences present in the drawings are not identified properly (see figures 1 and 13 for example).

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 10/272,929 and 60/329,759, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In this case, support for specifically altering amino acids M10, L13, Y62, M87 and L91 of MB-1 is supported in the prior applications (see paragraphs 0120-0121 of '929), however other specific alterations recited in the claims and provided in the present specification are not. Accordingly, the priority given to the instant claims is the filing date of the instant application, July 24, 2003.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

The recitation of “functional fragment” in claims 8 and 12 is indefinite because to what function is being referred is not clearly set forth in the claims nor the present specification. Dependent claims are included in the basis of the rejection because they simply set forth amino acids and size requirements of the fragment without clearly setting forth a function. Further, the recitation of “essential amino acid” is unclear and indefinite because it depends on which animal one would use the composition. The claim is indefinite because it is relevant to its intended use which is subject to change. Dependent claims are included in the basis of the rejection because while they set forth specific alterations, they fail to clarify functional fragments or address the metes and bounds directed to the intended use for defining “essential”.

Claim 9 is unclear and confusing because it appears to refer to the “essential” amino acid in claim 8, however it is not apparent what “analog” or “derivative” would be considered an essential amino acid. It does not appear to further limit claim 8. It is noted that other dependent claims set forth specific amino acid changes.



***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grundy *et al.* (1998-IDS reference)

Claims 8 and 12 broadly encompass any fragment of SEQ ID NO: 1, essentially any protein containing a methionine, lysine, threonine, leucine, tryptophan, arginine (claim 9). Grundy *et al.* disclose the protein sequence of MB-1. Homology comparisons of MB-1 disclosed in Figure 1 and that of SEQ ID NO: 1 indicate that the two sequences are homologous. Also compare Figure 1 of the instant specification with that of Figure 1 of Grundy *et al.* for a comparison of the resulting structures.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grundy *et al.* (1998-J. Biotech).

Claims 8 and 12 broadly encompass any fragment of SEQ ID NO: 1, essentially any protein containing a methionine, lysine, threonine, leucine, tryptophan, arginine (claim 9). Grundy *et al.* disclose the protein sequence of MB-1. Homology comparisons of MB-1 disclosed in Figure 1 and that of SEQ ID NO: 1 indicate that the two sequences are homologous. Also compare Figure 1 of the instant specification with that of Figure 1 of Grundy *et al.* for a comparison of the resulting structures.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Khoudi *et al.* Plant Physiol Biochem. 2005 Dec;43(12):1039-43. Epub 2005 Dec 13, "The de novo designed nutritive protein MB-1Trp does not resist proteolytic degradation in alfalfa leaves" provides post-filing evidence that the form of MB-1Trp alteration of MB-1 does not provide for a more stable protein with respect to some proteases, such as those extracted from alfalfa leaves.

#### ***Conclusion***

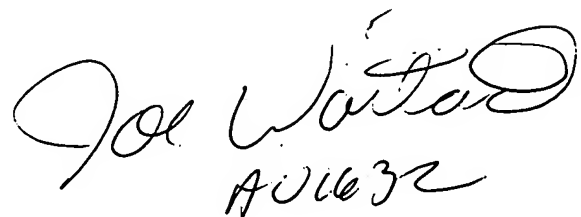
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach  
A01632